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Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the
Patent Application of:

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Gregory r. Shaw
Erik C. Gundersen
Laurel A. Christensen
Mead C. Killion

For: **HEARING TEST APPARATUS AND METHOD
HAVING AUTOMATIC STARTING FUNCTIONALITY**

Case Docket No. 12650US01

Enclosed are:

- X 5 sheets of drawings (informal);
- X 35 application pages (including 25 pages of specification, 9 pages of claims, and 1 page of Abstract).
- X Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. 1.9(F) and 1.27(c)) Small Business Concern
- X Declaration and Power of Attorney.

Attorney Docket No. 12650US01
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— Check in the amount of \$_____.

Basic Fee \$345.00

Additional Fees:

CLAIMS AS FILED

Number filed	Number Extra	Rate	Basic Fee
Total			\$345.00
Claims 40 - 20 =	20	\$9.00	\$180.00
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Claims 3 - 3 =	0	\$00.00	\$ 00.00
Total Filing Fee			<u>\$525.00</u>

Please charge the above total filing fee, and any additional fee required, to the deposit account of McAndrews, Held & Malloy, Ltd., Account No. 13-0017.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

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**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(F) AND 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Concern: ETYMOTIC RESEARCH, INC.

Address of Concern: 61 Martin Lane, Elk Grove Village, Illinois 60007

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled: HEARING TEST APPARATUS AND METHOD HAVING AUTOMATIC STARTING FUNCTIONALITY by inventors STEVEN J. ISEBERG, GREGORY R. SHAW, ERIK C. GUNDERSEN, LAUREL A. CHRISTENSEN and MEAD C. KILLION described in

- ☒ the specification filed herewith
☐ Application Serial No.
☐ Patent No. , issued.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities.
(37 CFR 1.27)

FULL NAME:

ADDRESS:

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Mead Killion

Title of Person Other Than Owner: President

Address of Person Signing: 61 Martin Lane, Elk Grove Village, Illinois 60007

Mead C. Killion
Signature

Date: Mar 7, 2000
(Mar 7, 2000 MCK)

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TITLE

HEARING TEST APPARATUS AND METHOD HAVING
AUTOMATIC STARTING FUNCTIONALITY

CROSS-REFERENCE TO RELATED APPLICATIONS

N/A

**STATEMENT REGARDING FEDERALLY SPONSORED
RESEARCH OR DEVELOPMENT**

N/A

BACKGROUND OF THE INVENTION

Hearing test devices that monitor the condition within a human ear are known. Such test devices generally require that the person performing the test (the "operator") place a test probe of the device within the ear canal of a test subject. Once the probe is placed properly within the ear canal, the operator activates the device, usually by pressing a button or the like. The device then emits test signals into the subject's ear through the probe in the ear canal. In response to the test signals emitted, the device receives response signals from the ear, likewise through the probe in the ear canal. Such response signals received are then used to determine whether the ear is functioning properly.

One such test device analyzes the distortion product otoacoustic emissions (DPOAE) generated by the ear to determine middle ear function. More specifically, a DPOAE test device generates and emits two audible tones (i.e., test signals) at different frequencies into the ear canal of a subject. A healthy ear will produce, in response to the two audible tones, a response signal having a frequency that is a combination

of the frequencies of the two audible tones. Thus if the two audible tones generated have frequencies of f_1 and f_2 , respectively, a healthy subject's ear will emit a response signal having a frequency that is a combination of f_1 and f_2 . The strongest response signal occurs at a frequency of $(2)(f_1)-f_2$, and is referred to as the distortion product.

In addition, DPOAE test devices also generally modify the frequencies of the audible tones transmitted into the ear canal over time during the course of the test. In response, a healthy subject's ear will emit a distortion product having a frequency that similarly changes over time during the course of the test. Generally speaking, the lack of distortion product otoacoustic emissions from the ear during the course of the test is an indication of possible hearing loss.

Existing DPOAE test devices all use a probe that is inserted into the ear canal of the test subject. Such a probe is either attached to the device via a cable, or is mounted on the device to form an integrated hand-held device. In either case, proper placement of the probe into the ear canal is critical to obtaining accurate and useful DPAOE measurements. This is primarily due to the fact that otoacoustic emissions produced by a healthy ear are extremely small in magnitude, typically in the range from -10dB SPL to $+20\text{dB SPL}$. Improper placement of the test probe in the ear canal may result in the inadvertent masking of the emissions (and thus the triggering of a false negative response), in an inaccurate measurement, or in an otherwise invalid result.

Proper placement of the test probe in the ear canal is generally determined by one or more of several factors. An operator may be required to insert the probe deeply into the ear canal and/or to create a seal between the probe and the ear canal. An operator may also be required to ensure that the probe is not blocked by a collapsed ear canal, by the canal wall itself, or by earwax. In addition, the operator may also

be required to determine that, once the probe is inserted, the resulting volume of the ear canal is within a certain desirable range.

Consequently, it is often very difficult for an operator to know whether proper placement of the probe has been achieved before the operator initiates the testing process. Moreover, particularly in the case of an integrated hand-held device, the act of initiating the test (e.g., pressing a start button) may shift the placement of the probe in the ear canal, which in and of itself may cause an inaccurate measurement. As a result, an operator may be required to perform several tests in order to obtain accurate measurements, greatly slowing down the testing process.

In addition, in some cases, these problems may prevent an accurate measurement altogether. Specifically, a large proportion of DPOAE testing is performed on infants. Typically, the infant is asleep when the testing is performed so that movement (and thus noise) is minimal. The process of properly placing and positioning the probe into an infant's very small ear canal for the amount of time and number of iterations needed to obtain accurate results often wakes the infant, which often makes the test impossible to complete, particularly if the infant is crying.

Therefore, it is an object of the present invention to provide a test operator with an indication that the testing probe is properly placed within the test subject's ear canal.

It is also an object of the present invention to provide automatic initiation or starting of the test once the probe has been properly placed within the test subject's ear canal.

SUMMARY OF THE INVENTION

These and other objects of the invention are achieved in a hearing test device that transmits pre-hearing test condition analysis stimuli into the ear canal of a test subject. The device analyzes signals

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received from the ear canal in response to the stimuli, and determines from the stimuli a condition or conditions related to the position of the testing probe in the ear canal. If the condition or conditions are satisfied, the device automatically begins a hearing test. Satisfaction of the condition or conditions as such generally indicates that the testing probe is placed properly in the ear canal.

In one embodiment, the condition comprises a temporal stability condition, which is a measure of the stability of the testing probe in the ear canal. If it is determined that the testing probe is stable (i.e., stationary for a period of time) in the ear canal, the temporal stability condition is satisfied.

In another embodiment, the condition comprises a spectral response condition, which is a measure of the seal of the testing probe and of the volume of the ear canal. If it is determined that the testing probe is sealed in the ear canal and the volume of the ear canal is within an acceptable range, the spectral response condition is satisfied.

In yet another embodiment, the condition comprises a channel balance condition, which is a determination of whether any blockages exist in the sound delivery system. If a response is not received to one of the stimuli, then a blockage is assumed. If the responses received are within an acceptable range, then the condition is satisfied.

The hearing test device also includes a display that provides an indication of the volume behind the testing probe, as well as the noise being received by the device, to assist the operator in properly positioning the testing probe in the test subject's ear canal.

These and other advantages and novel features of the present invention, as well as details of an illustrated embodiment thereof, will be more fully understood from the following description and drawings.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates an integrated, hand-held hearing test or screener device built in accordance with the present invention. The device 1 includes a housing or terminal portion 3, an isolation body or assembly 5 and a testing probe 7. The testing probe 7 includes an ear tip 9, which may be made of an elastic material, such as, for example, rubber. The testing probe 7 is integrated with the terminal portion 3 via the isolation body 5, which elastically couples or suspends the testing probe from the terminal portion 3. Additional detail regarding the isolation body 5 can be found in copending U.S. patent application Serial No. 09/285,938 filed April 2, 1999, which application is incorporated herein by reference in its entirety. While the testing probe 7 is illustrated in Fig.1 as being integrated with the terminal portion 3, the testing probe 7 may be separate from the terminal portion 3 and connected to the terminal portion 3 via a cable (not shown). In addition, the device 1 itself may also be a stationary (i.e., not hand-held) device having a probe connected thereto via a cable, as is known in the art.

Referring again to Fig.1, the terminal portion 3 includes a handle portion 11, a keyboard 13 and a display 15, which may be, for example, an LCD display. An operator grasps the handle portion 11, and manipulates the keyboard 13 with the operator's thumb (or forefinger). The operator may view the display 15 before, during and after the test. The terminal portion 3 also includes a data port (not shown) located on an underside of the handle portion 11. The data port enables the device 1 to be communicatively coupled to an external device, such as, for example, a personal computer, for download of test and related data or upload of programming or other information. The terminal portion 3 may also include additional visual indicators 19 (besides the display 15), such as, for example, light emitting diodes (LEDS), for indicating to the

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operator, for example, test status or the like. In Fig. 1, visual indicators 19 illustrate a "ready" status, a "test" status, and an "error" condition.

To perform a test, an operator grasps the handle portion 11 of the terminal portion 3 and moves the device 1 towards a test subject's ear (not shown). The operator then places the testing probe 7 into the subject's ear such that the ear tip 9 is seated within the subject's ear canal.

As explained more completely below, a pre-test condition analysis is initiated that determines whether certain condition(s) are satisfied, indicating that the testing probe is properly placed in the ear. Such analysis may be initiated automatically when the device is activated, or, automatically or by the operator when the testing probe 7 is placed in the subject's ear. In any case, if all condition(s) are satisfied, the actual ear test is automatically started by the device 1, without requiring operator input.

Fig. 2 is a block diagram of a hearing test or screener device built in accordance with the present invention. The block diagram of Fig. 2 is one embodiment of the device 1 of Fig. 1, which may be used, for example, to perform DPOAE testing, as discussed above. Of course, other embodiments exist that may not incorporate all of the components shown in Fig. 2, or that may incorporate components that are different than, or components in addition to, those shown in Fig. 2.

The embodiment of Fig. 2 will now be discussed with reference to DPOAE testing. A digital signal processor (DSP) 21 generates digital signals representative of two audio tones of different frequencies and transmits the digital signals to a CODEC block 23 (i.e., an analog to digital and digital to analog converter), which converts the digital signals to electrical signals. The electrical signals are transmitted to an audio source 25, which may be, for example, located in the testing probe 7 of Fig. 1. The audio source 25 may comprise, for example, two audio

speakers. The two audio speakers respectively transduce electrical signals into audible tones that are transmitted into the ear canal of a test subject. A microphone 27, which may, for example, be located in the testing probe 7 of Fig. 1, receives responsive audio signals from the ear of the test subject, and transduces the received audio signals into electrical signals representative of the received audio signals. The electrical signals are amplified by a microphone preamplifier 29, converted into digital signals by the block 23, and then communicated to the DSP 21. The DSP 21 then uses the signals to perform DPOAE analysis as is known in the art.

The DSP 21 also communicates output signals to the LCD Display Driver 31 which causes display of output data on the liquid crystal display 33 and/or indication of test status on visual indicators (e.g., LEDs) 35. In general, the output data comprises, for example, test results or the like. Output data, as such, may be displayed before, during and after the test. In fact, as discussed more completely below, the display may be used by an operator before the test to assist in properly placing the testing probe into the ear canal.

An operator may also use a headphone to further assist with proper placement of the testing probe in the ear. In one embodiment, the DSP 21 communicates digital signals (e.g., representative of the audio signals received from the ear) to a D/A converter 37 which converts the digital signals into electrical signals. The electrical signals are then amplified by the amplifier 39 and communicated to a headphone output 41. The headphone output 41, which may be, for example, headphone jack 17 shown in Fig. 1, is connected to a headphone assembly (not shown), which transduces the electrical signals into audio signals. Alternatively, the headphone output may be located adjacent the data port on the underside to the handle portion 11. With such a configuration, an operator may, for example, monitor the audio signals

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received from the ear to assist in the positioning and repositioning of the probe within the ear canal. Additional detail regarding audibly monitoring the condition in the ear can be found in copending U.S. patent application Serial No. 08/971,520 filed November 17, 1997, which application is incorporated herein by reference in its entirety.

In a further embodiment, discussed more completely below, the DSP 21 communicates status signals, to the headphone output 41, which signals can be audibly monitored by an operator via the headphones, to assist with the positioning of the probe within the ear canal.

The DSP 21 also downloads or uploads data via the data port by communication with the RS-232 driver 43. In addition, keypad 44 enables an operator to enter data and/or commands into the device 1.

As mentioned above, the actual testing phase performed by the testing device is automatically started after the testing probe has been placed in the ear canal and upon the completion of a pre-test condition analysis. In other words, the device does not begin the actual test until it determines that the testing probe has been properly placed in the ear canal.

Such auto-start functionality simplifies the testing procedure. Since the actual hearing test begins once it is determined that the probe is properly placed in the ear canal and without requiring further action by the operator, there is a greater chance that accurate data will be generated by the first hearing test attempt. As mentioned above, this is particularly important for infants, who are most often tested while they are sleeping. In addition, such auto-start functionality eliminates the potential movement problems associated with the operator pressing a button to initiate a test while the probe is in the subject's ear. This is particularly true for a hand-held device such as that shown in Fig.1, since the action of depressing a key often results in inadvertent probe movement.

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Fig. 3, is a flow chart illustrating generically the auto-start feature of the present invention. The functionality of Fig. 3 may be implemented using a digital signal processor. As mentioned above, the auto-start feature of the present invention involves a pre-hearing test condition analysis. The analysis begins by application of a series of stimuli to the subject's ear (block 45) by a source, such as, for example, a speaker. A receiver, such as, for example, a microphone receives responsive signals from the ear, which are measured both over time and frequency. The measured signals are then used to perform one or more tests (blocks 47, 49, 51) to determine whether certain condition(s) exist (or do not exist, as the case may be) that indicate proper placement of the probe within the ear canal. If any one of the tests are failed (or if the single test is failed if only one test is being performed), the process begins over again by application of the stimuli at block 45. If, however, all of the tests are passed (or if the single test is passed if only one test is being performed), indicating that the proper condition(s) are present, the actual hearing test (e.g., a DPOAE test) is automatically initiated (block 53).

Fig. 4 is a flow chart illustrating the auto-start feature of the present invention, in which tests are performed to analyze four pre-start conditions, namely, temporal stability, low frequency roll-off, noise limit, and channel balance. The functionality of Fig. 4 may be implemented by the hearing test or screener device of Figs. 1 and 2.

The analysis begins by the application of stimuli to the ear canal (block 55) via the source or speakers 25 of Fig. 2. As discussed above, the stimuli is generated by the DSP 21 of Fig. 2. Such stimuli may, for example, be alternating 300 Hz and 1KHz audio tones. Such stimuli may also be non-audio stimuli. The microphone 27 receives responsive signals from the ear which are measured over time by the DSP 21 and used to perform condition tests.

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The first test performed is determining the temporal stability condition (block 57). The general purpose of this test is to estimate when the position of the probe is stationary in the ear canal. Probe movement changes the geometry of the enclosed space in the ear behind the end of the probe tip, and thus changes the magnitude of the response received from the ear. When the magnitude of such response is consistent over time, temporal stability is assumed (i.e., the temporal stability condition is satisfied).

Referring to block 57 of Fig. 4, if it is determined that the probe is unstable, the temporal stability condition test begins over again at block 55. If, however, it is determined that the probe is stable, the next test is initiated. Additional detail regarding determining the temporal stability condition is set forth below.

The next test performed is determining the low frequency roll-off condition, i.e., whether the response received from the ear exhibits any low frequency roll-off (block 59). The low frequency roll-off condition may also be referred to as the spectral response condition. The general purpose of this test is to determine when the probe has formed a proper seal in the ear canal. When a probe is not completely sealed to the ear canal, the low frequencies (usually $<500\text{Hz}$) show a pronounced decrease in magnitude. The lowest frequencies show the greatest decrease in magnitude, gradually decreasing as frequency increases. This condition is known as low-frequency roll-off. When the shape of the low frequency component of the response is determined to be within an acceptable range, the condition is satisfied. In making such a determination, both the slope of the low frequency component of the response and the range of values received may be considered.

Referring to block 59 of Fig. 4, if it is determined that the response exhibits low frequency roll-off, the process begins over again at block 55. If, however, it is determined that low-frequency roll-off is

sufficiently absent from the response, the next test is initiated. Additional detail regarding determining the spectral response condition is set forth below.

The next test performed is determining whether any background noise is received along with the response from the ear (block 61). The general purpose of this test is to delay the starting of the hearing test if there is significant background noise present. A noise floor of the response may be determined from a frequency band where there is no stimuli energy. In one embodiment, the noise floor is calculated at the lowest frequency to be tested. When the noise floor is below an acceptable level, the test is passed. In general, if the noise level is too high, for example, if there is background noise in the test room or if the test subject is swallowing or coughing, the actual hearing test is delayed. Otherwise, the unwanted noise may mask the signals needed to perform the actual hearing test.

Referring to block 61 of Fig. 4, if it is determined that the noise floor is above the limit, the process begins over again at block 55. If, however, it is determined that the noise floor is below the limit, the next test is initiated.

The next test performed is determining the channel balance condition, i.e., whether any blockages exist in the sound delivery system (block 63). A set of stimuli is applied in an alternating fashion by the sound source (e.g., two speakers), and the response received from the ear canal is measured. If one of the responses is not received, then it is assumed that a blockage exists. In general, this test is passed when the responses received as a result of each speaker are within an acceptable range.

Referring to block 63 of Fig. 4, if the responses are not within an acceptable range, it is assumed that the channels are unbalanced and the process begins over again at block 55. If, however, the responses are

within an acceptable range, it is assumed that the channels are balanced and the actual hearing test is started (block 65).

Thus, as can be seen in Fig. 4, the actual hearing test automatically starts if and only if all of the pre-hearing test or pre-start conditions are satisfied. A system such as in Fig. 4 may, however, incorporate an override feature that enables the actual hearing test to be started without performance of one or more of the condition tests. Such an override feature may be used in situations where a test subject's physiology prevents passage of one or more of the condition tests. For example, if a test subject has a pressure equalization tube in the subject's tympanic membrane, the apparent ear canal volume would be abnormally large, preventing the actual hearing test from starting (e.g., the spectral response condition test would be failed). In one embodiment, the override feature is implemented so that a particular condition test (or tests) is disabled and thus skipped. In another embodiment, all condition tests are disabled, in which case the actual hearing test is manually initiated by the operator.

In addition, as can be seen from Figs. 3 and 4, the overall testing process involves two phases, the auto-start phase, during which the condition tests are performed, and the hearing test phase, during which an actual hearing test (such as a DPOAE test discussed above) is performed. To assist an operator in positioning the probe in the ear canal during the auto-start phase, feedback may be provided to the operator. Such feedback informs the operator of the status of the auto-start phase, and may take the form of visual queues, auditory queues, or both. Examples of visual queues include light indicators (such as visual indicators 19 of Fig. 1), text messages provided on a display (such as display 15 of Fig. 1), and graphical outputs provided on such a display. Examples of auditory queues include audible tones, generated speech queues, and the actual response measured by the microphone (such as

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the microphone 27 of Fig. 2). Such auditory queues may be presented to the operator via external headphones, as discussed above with respect to Fig. 2, and may comprise distinctive sounds for each condition test performed during the auto-start phase.

While Fig. 4 shows four condition tests being performed, it should be understood that any number of those tests can be implemented in any given system. For example, following this description and prior to the claims is 6 pages of an exemplary computer code listing (hereinafter referred to as "the Code") in which only the condition tests of blocks 57, 59 and 63 of Fig. 4, namely, the temporal stability condition test, spectral response condition test, and receiver balance condition test, are performed. The Code is one embodiment of the auto-start phase that may be used by the device of Figs. 1 and 2, and is being submitted as part of the specification pursuant to 37 C.F.R. §1.96(b)(2).

The auto-start phase as set forth in the Code may be described as follows. The stimuli applied to the ear canal consists of two pure tones at different frequencies (F1, F2), with one tone applied per speaker. The tones F1 and F2 may be 300Hz and 1000Hz, for example. The response is measured over a fixed interval of time. The frequency of the tones are then reversed on the speakers and the response is measured again. This complete sequence is completed at least once, resulting in each speaker sending out four tones. Specifically, this complete sequence may be illustrated as follows:

Stimuli #	Speaker A	Speaker B
n-3	F1	F2
n-2	F2	F1
n-1	F1	F2
n	F2	F1

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where n is the most recent stimuli. The stimuli may be applied every one-third of a second, for example, resulting in a complete sequence time of 1.2 seconds.

The complete sequence, therefore, starts with the initiation of the first stimuli (n-3), where Speaker A transmits a tone at F1 (e.g., 300Hz) and speaker B transmits a tone at F2 (e.g., 1000Hz). One third of a second later, the second stimuli (n-2) is initiated, where speaker A transmits a tone at F2 (1000Hz) and speaker B transmits a tone at F1 (300Hz). One third of a second later, the third stimuli (n-1) is initiated, where speaker A again transmits a tone at F1 and speaker B transmits a tone at F2. Finally, after another one third of a second, the fourth stimuli (n) is initiated, where again speaker A transmits a tone at F2 and speaker B transmits a tone at F1.

Next, the responses to each tone transmitted are measured, where $P_i(n)$ is the measured pressure (in dB) at frequency F_i for each stimuli n. The pressure values (i.e., responses) are then used to perform the condition analysis.

More particularly, with regard to the temporal stability condition, the responses from each speaker are compared over time at each frequency according to the following equations:

$$\text{Speaker A} \quad | P1(n-1) - P1(n-3) | \leq \text{fit_bal2} \quad (F1)$$

$$| P2(n) - P2(n-2) | \leq \text{fit_bal2} \quad (F2)$$

$$\text{Speaker B} \quad | P1(n) - P1(n-2) | \leq \text{fit_bal2} \quad (F1)$$

$$| P2(n-1) - P2(n-3) | \leq \text{fit_bal2} \quad (F2)$$

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where fit_bal2 is the temporal balance parameter (in dB). The value of the temporal balance parameter, which may be, for example 2dB, establishes how closely the response at each frequency must match in order to conclude that the probe is stable.

Specifically, for speaker A, the difference between the responses for the first tone (F1) (i.e., the difference in pressure resulting from the first and third stimuli) is calculated. Also, the difference between the responses for the second tone (F2) (i.e., the difference in pressure resulting from the second and fourth stimuli) is calculated. The same two calculations are also performed for speaker B. If all four calculated values are no greater than 2dB, for example, then the temporal stability test is passed, and the conditional analysis proceeds to the spectral response condition test.

The spectral response condition test determines the difference in the response as a function of frequency, according the following equations:

$$| P2(n) - P1(n-1) | \leq \text{fit_bal3} \quad \text{Speaker A}$$

$$| P1(n) - P2(n-1) | \leq \text{fit_bal3} \quad \text{Speaker B}$$

where fit_bal3 is the spectral response parameter (in dB). In other words, the response generated by each speaker is compared at different frequencies (e.g., 300Hz v. 1000Hz) to determine if a leak in the probe seal exists. If the calculated difference between the response generated by each speaker is no greater than say, for example, 25dB, then it is assumed that no leak is present.

The spectral response condition test also determines the average receiver response to the first tone (F1) according to the following equation:

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$$\begin{array}{ccc} \text{Speaker} & B & A \\ \text{fit_min} \leq |(P1(n) + P1(n-1)) / 2| \leq \text{fit_max} \end{array}$$

where fit_min is the minimum spectral response at F1 (in dB) and fit_max is the maximum spectral response at F1 (in dB). This calculation is essentially a test of the volume of the ear canal. If the average response is within an acceptable range (e.g., between 32 dB and 50.5 dB), then the volume is of the size expected from an ear canal. If the average response is greater than the range, the volume is too small, indicating a blocked or partially blocked condition. If the average response is below the range, the volume is too large, indicating that the probe is not in the ear canal (or not far enough in).

When the "leak" and "volume" portions of the spectral response condition test are passed, it is assumed that the probe is placed a proper distance in the ear canal and the probe is properly sealed to the canal. The condition analysis then proceeds to the channel balance condition test.

The channel balance condition test compares the response generated by each speaker at the same frequency according to the following equation:

$$\begin{array}{ccc} \text{Speakers} & B & A \\ |P1(n) - P1(n-1)| \leq \text{fit_bal1} & (F1) \end{array}$$

$$\begin{array}{ccc} \text{Speakers} & A & B \\ |P2(n) - P2(n-1)| \leq \text{fit_bal1} & (F2) \end{array}$$

where fit_bal is the receiver balance parameter (in dB). In other words, the response generated by tone F1 is compared at each speaker, and the response generated by tone F2 is compared at each speaker. If both comparisons result in a value of no greater than 4dB, for example, then it is assumed that both speakers are functioning (e.g., neither is blocked). Once this test is passed, the actual hearing test is automatically started.

Again, in the present embodiment, all condition tests must be passed for the actual hearing test to be automatically started. If any fail, the process begins over again by the transmission of two more sets of tones are transmitted (corresponding to fifth and sixth stimuli). The responses are then reevaluated. Specifically, fifth and sixth sets of responses are generated, and they are used with the third and fourth sets of responses in performing the condition tests over again. The first and second sets of responses are discarded. If one of the condition tests is again failed, two more sets of tones are transmitted (corresponding to seventh and eighth stimuli), and seventh and eighth sets of responses are generated. They are used with the fifth and sixth sets of responses in performing the condition tests over again. The third and fourth sets responses are discarded. This process is repeated until all condition tests are passed.

As mentioned above, it may be desirable to provide the operator feedback during the auto-start phase of the testing process. The Code provides for display of data to assist the operator in positioning the probe in the ear canal. Fig. 5 depicts screens that illustrate, via bar graph, volume and noise levels measured by the device. Screen 71 shows a condition where the noise and volume are high, indicating that the probe has not yet been placed in the ear canal. Screen 73 shows a condition where the noise and volume are lower, indicating to the operator that, while the probe is being positioned in the ear canal, it has not been inserted properly (e.g., the probe is not deep enough and not

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sealed to the ear canal). Screen 75 shows a condition where the noise and volume are relatively low, indicating to the operator that the positioning is likely proper, and that the actual hearing test may be started soon. Of course, other types of outputs on the display are also possible, as mentioned above, to assist the operator.

Many modifications and variations of the present invention are possible in light of the above teachings. Thus, it is to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as described hereinabove.

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"SUBMISSION OF COMPUTER PROGRAM LISTING
AS PART OF THE SPECIFICATION
PURSUANT TO 37 C.F.R. §1.96(b)(2)

```
~~~~~ deleted code

F1seal      equ      300.0      ; test frequency #1
F2seal      equ      1000.0     ; test frequency #2
V12_Seal    equ      0.1        ; normalized seal voltage for P1 and P2 (was 0.03)

fit_bal1    equ      4.0/256.0  ; maximum difference between receiver responses
fit_bal2    equ      2.0/256.0  ; maximum retest difference for each receiver
fit_bal3    equ      25.0/256.0 ; max value for abs(P1-P2) for each receiver
fit_min     equ      32.0/256.0 ; minimum SPL/256 response for seal test
fit_max     equ      50.5/256.0 ; maximum SPL/256 response for seal test
max_seal_tries equ      60      ; number of times to try seal
```

org y:

```
~~~~~ deleted code

; variables for autostart

; results from test (n-1)
chanA1      dc      0           ; Response at F1seal
chanB1      dc      0           ; Response at F2seal

; results from test (n)
chanA2      dc      0           ; Response at F1seal
chanB2      dc      0           ; Response at F2seal

; results from test (n-3)
chanA1old   dc      0
chanB1old   dc      0

; results from test (n-2)
chanA2old   dc      0
chanB2old   dc      0

seal_attempts dc      0
```

org p:

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; test (n) - output tone on each receiver and measure response
; Receiver #1 - F2seal Receiver #2 - F1seal

~~~~~ deleted code

;       calculate P1

~~~~~ deleted code

move a1,y:chanA2

; calculate P2

~~~~~ deleted code

move            a1,y:chanB2

; test current results for channel fit

; if (chanA1+chanB2)/2 < fit\_min ; fail ; else next test

move            y:chanA1,a

move            y:chanB2,b

add            b,a

asr            a                    ; (chanA+chanB)/2

~~~~~ deleted code

cmp #>fit_min,a

jle retest

; if (chanA1+chanB2)/2 > fit_max ; fail ; else OK

~~~~~ deleted code

cmp            #>fit\_max,a

jgt            retest

; test for channel balance (freq #1)

; if abs(chanA1-chanB2) < chan\_bal db pass, else fail

~~~~~ deleted code

move y:chanA1,a

move y:chanB2,b

sub b,a

move #fit_bal1,b

cmpm b,a

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jgt retest

; test for channel balance (freq #2)
; if abs(chanA2-chanB1) < chan_bal db pass, else fail

move y:chanA2,a
move y:chanB1,b
sub b,a
move #fit_bal1,b
cmpm b,a
jgt retest

; test difference between P1 and P2
; if abs(chanA1-chanA2) < chan_bal db pass, else fail (use same reciever)

~~~~~ deleted code

move            y:chanA1,a  
move            y:chanA2,b  
sub             b,a  
move            #fit\_bal3,b  
cmpm            b,a  
jgt             retest

; test difference between P1 and P2  
; if abs(chanB1-chanB2) < chan\_bal db pass, else fail (use same reciever)

move            y:chanB1,a  
move            y:chanB2,b  
sub             b,a  
move            #fit\_bal3,b  
cmpm            b,a  
jgt             retest

; compare previous results  
; channel A

~~~~~ deleted code

move y:chanA1,a
move y:chanA1old,b
sub b,a
move #fit_bal2,b
cmpm b,a
bgt retest ; retest

move y:chanA2,a
move y:chanA2old,b
sub b,a

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```

    move    #fit_bal2,b
    cmpm    b,a
    bgt     ; retest

; channel B
    move    y:chanB1,a
    move    y:chanB1old,b
    sub     b,a
    move    #fit_bal2,b
    cmpm    b,a
    bgt     ; retest

    move    y:chanB2,a
    move    y:chanB2old,b
    sub     b,a
    move    #fit_bal2,b
    cmpm    b,a
    bgt     ; retest

    bra     fun2 ; proceed to calibration phase of test

retest

; noise bar graph
    move    #normalized_dft_average+6,r1
    jsr     dbspln ; A = noise power dB SPL/256.0
    Hbar_Acc #NOISE_TABLE
    move    #mes2a+4,r2 ; R590 put info on second line for now
    jsr     move_string

; volume graph R590
    move    y:chanB2,a
    Hbar_Des #VOLUME_TABLE
    move    #mes2a+12,r2 ; R590 put info on second line for now
    jsr     move_string

    move    #mes2a,r1
    jsr     screen ; show bar graph

    bset    #LED2,x:M_HDR
    bset    #LED3,x:M_HDR

; test for max retries
    move    y:seal_attempts,a
    add     #>1,a
```

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```
cmp      #>max_seal_tries,a
bgt      power_off
move     a,y:seal_attempts
```

```
; update old values
```

```

move      y:chanA1,a          ; save results for next pass
move      a,y:chanA1old
move      y:chanB1,a
move      a,y:chanB1old

```

```

move      y:chanA2,a          ; save results for next pass
move      a,y:chanA2old
move      y:chanB2,a
move      a,y:chanB2old

```

bra fun1_loop

endsec

~~~~~ deleted code

**CLAIMS:**

1. A hearing test device comprising:
  - a testing probe for insertion into an ear canal of a test subject;
  - a stimuli source for transmitting stimuli into the ear canal;
  - a receiver for receiving response signals from the ear canal in response to the transmitted stimuli; and
  - a processor for determining from the response signals whether at least one condition related to the position of the testing probe in the ear canal is satisfied, and for automatically starting a hearing test if the at least one condition is satisfied.
2. The hearing test device of claim 1 wherein the stimuli source comprises two audio speakers, and wherein the receiver comprises a microphone.
3. The hearing test device of claim 2 wherein the stimuli comprise a plurality of pure audio tones.
4. The hearing test device of claim 3 wherein the plurality of pure audio tones are at two alternating frequencies.

5. The hearing test device of claim 4 wherein the two alternating frequencies comprise approximately 300Hz and approximately 1000 Hz.
6. The hearing test device of claim 1 wherein the at least one condition comprises a temporal stability condition.
7. The hearing test device of claim 6 wherein the temporal stability condition is satisfied when the response signals are consistent in magnitude over a period of time.
8. The hearing test device of claim 7 wherein consistent in magnitude comprises being within approximately 2dB.
9. The hearing test device of claim 1 wherein the at least one condition comprises a spectral response condition.
10. The hearing test device of claim 9 wherein the spectral response condition is satisfied when the difference between at least two of the response signals generated from stimuli at two different frequencies is no greater than a predetermined value, and the average of at least two of the response signals generated from stimuli at a single frequency is within a preselected range.

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11. The hearing test device of claim 10 wherein the predetermined value comprises approximately 25dB.

12. The hearing test device of claim 10 wherein the preselected range is between approximately 32dB and 50dB.

13. The hearing test device of claim 1 wherein the stimuli source comprises first and second audio speakers, each on a separate audio channel.

14. The hearing test device of claim 13 wherein the at least one condition comprises a channel balance condition.

15. The hearing test device of claim 14 wherein the channel balance condition is satisfied when the difference between at least two response signals generated in response to the transmission of at least one stimulus by each of the first and second audio speakers is no greater than a predetermined value for at least one frequency.

16. The hearing test device of claim 1 wherein the at least one condition comprises a plurality of conditions, and wherein the plurality of conditions comprise at least a temporal stability condition, a spectral response condition, and a channel balance condition.



17. The hearing test device of claim 1 wherein the hearing test comprises a distortion product otoacoustic emissions test.

18. The hearing test device of claim 15 wherein the predetermined value is approximately 4dB.

19. The hearing test device of claim 1 wherein the processor, if the at least one condition is not satisfied, automatically causes the transmission of additional stimuli for re-determining from at least signals responsive to the additional stimuli whether the at least one condition has been satisfied.

20. A method of starting a hearing test, the method employed by a hearing test device having a testing probe positioned in an ear canal of a test subject, the method comprising:

transmitting a plurality of stimuli into the ear canal;

receiving a plurality of response signals from the ear canal in response to the plurality of stimuli;

performing, using at least a portion of the plurality of response signals, at least one test related to the position of the testing probe in the ear canal; and

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automatically starting a hearing test if the at least one test is passed.

21. The method of claim 20 wherein the at least one test comprises determining whether the testing probe is stationary in the ear canal.

22. The method of claim 21 wherein the at least one test is passed when the magnitude of the plurality of response signals is consistent over time.

23. The method of claim 22 wherein consistent comprises being within approximately 2dB.

24. The method of claim 20 wherein the at least one test comprises determining whether the testing probe is properly sealed in the ear canal.

25. The method of claim 24 wherein the at least one test is passed when the difference between at least two of the plurality of response signals generated from stimuli at two different frequencies is no greater than a predetermined value.

26. The method of claim 25 wherein the predetermined value is approximately 25dB.

27. The method of claim 20 wherein the at least one test comprises determining whether the volume of the ear canal is within a predetermined range.

28. The method of claim 27 wherein the at least one test is passed when the average of at least two of the plurality of response signals generated from stimuli at a single frequency is within a predetermined range.

29. The method of claim 28 wherein the predetermined range is between approximately 32dB and 50dB.

30. The method of claim 20 wherein the at least one test comprises determining whether first and second channels are balanced.

31. The method of claim 30 wherein the at least one test is passed when the difference between at least two of the plurality of response signals generated in response to at least one stimulus on each of the first and second channels is no greater than a predetermined value for at least one frequency.

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32. The method of claim 31 wherein the predetermined value comprises approximately 4dB.

33. The method of claim 20 wherein the at least one test comprises a plurality of tests, and wherein the plurality of tests comprises determining whether the testing probe is stationary in the ear canal, whether the testing probe is properly sealed in the ear canal, whether the volume of the ear canal is within a predetermined range, and whether first and second channels transmitting the plurality of stimuli are balanced.

34. The method of claim 20 wherein the hearing test is a distortion product otoacoustic emissions test.

35. The method of claim 20 further comprising displaying an indication of the volume of the ear canal.

36. The method of claim 35 wherein the indication is a bar graph.

37. The method of claim 20 further comprising displaying an indication of the amount of noise being received by the hearing test device.

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38. The method of claim 37 wherein the indication is a bar graph.
39. The method of claim 20 further comprising:
- (a) automatically transmitting a further plurality of stimuli into the ear canal if the at least one test is not passed;
  - (b) receiving a further plurality of response signals from the ear canal in response to the further plurality of stimuli;
  - (c) performing, using at least the further plurality of response signals, the at least one test related to the position of the testing in the ear canal;
  - (d) automatically starting a hearing test if the at least one test is satisfied; and
  - (e) repeating steps (a) through (d) if the at least one test is not satisfied.
40. A method of starting a hearing test, the method employed by a hearing test device having a testing probe positioned in an ear canal of a test subject, the method comprising:
- (a) determining whether the testing probe is properly positioned in the ear canal;
  - (b) automatically starting a hearing test if it is determined that the testing probe is properly positioned in the ear canal; and

(c) automatically repeating steps (a) and (b) if it is determined that the testing probe is not properly positioned in the ear canal.

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**ABSTRACT**

A hearing test device and method are disclosed which involve the placement of a testing probe in the ear canal of a test subject. The device analyzes responses to stimuli applied to the ear canal to determine whether the testing probe has been properly placed in the ear canal. The device may determine, for example, whether the probe is stable, whether it is sealed in the ear canal, whether the resulting volume of the ear canal is acceptable, and/or whether the stimuli delivery system is blocked in any way. If the device determines that the testing probe has been properly placed in the ear canal, the device automatically starts a hearing test without requiring any operator input.







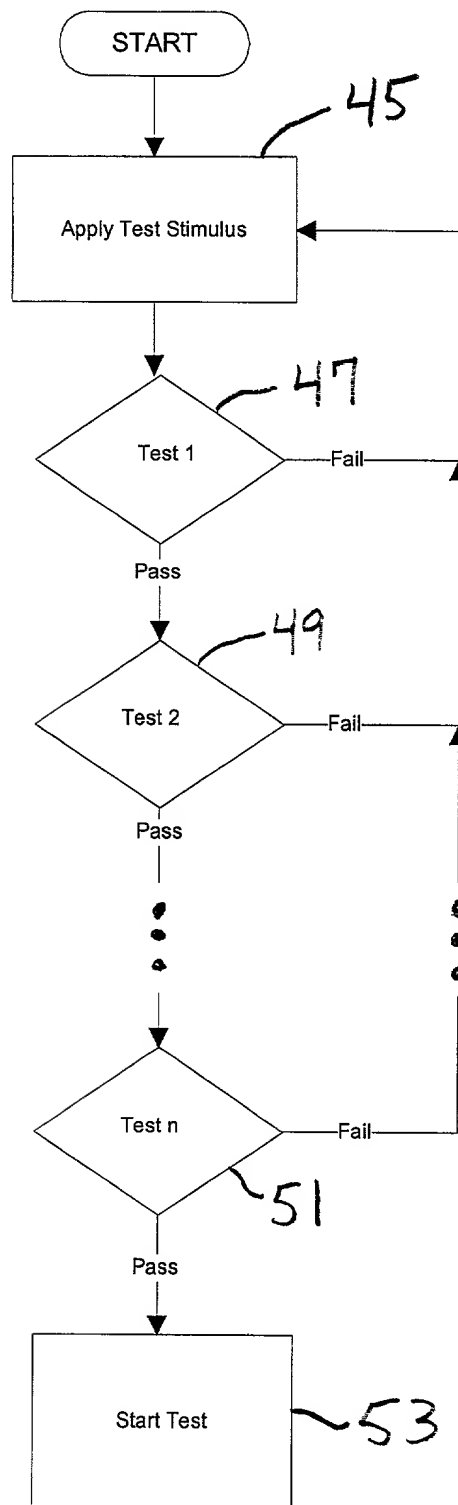


FIG. 3

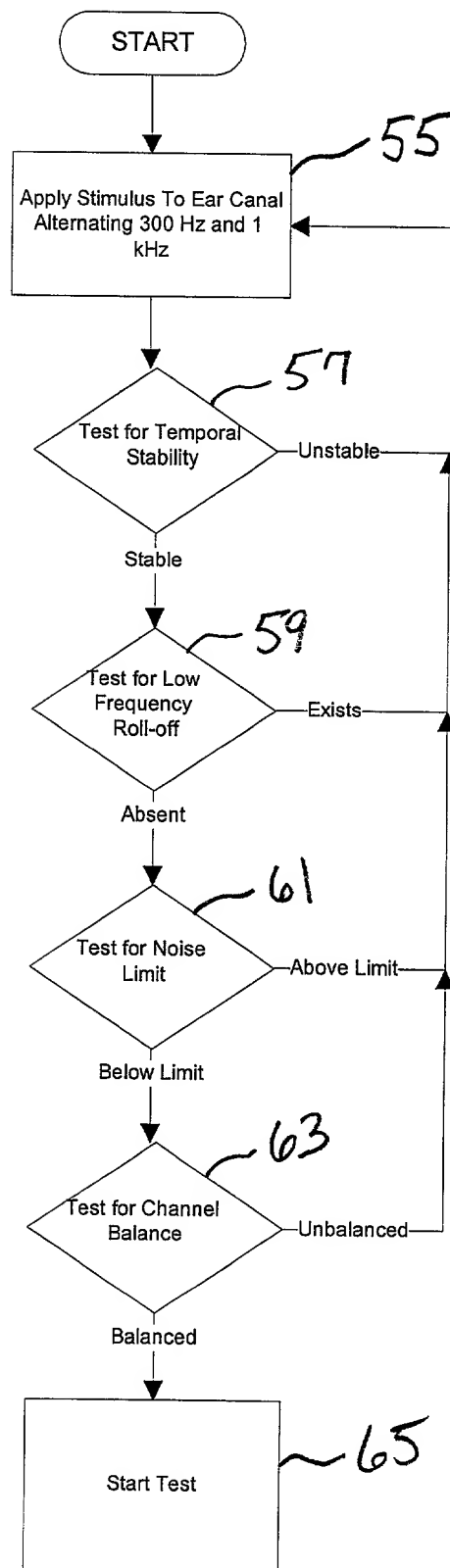


FIG. 4

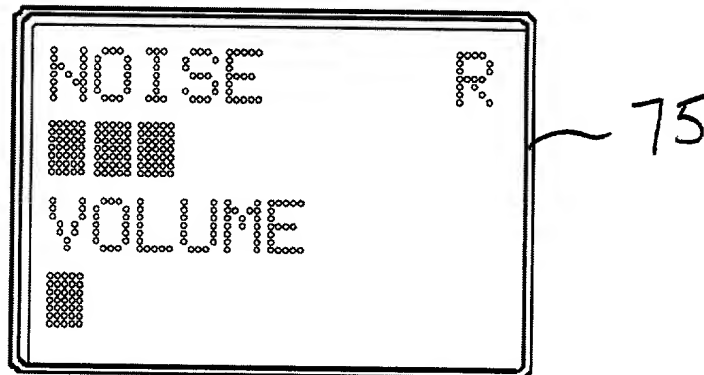
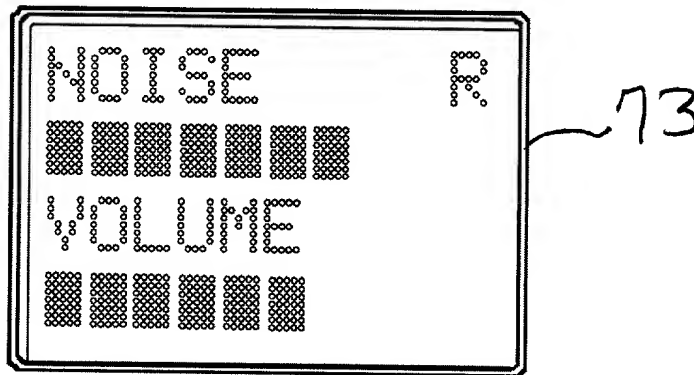
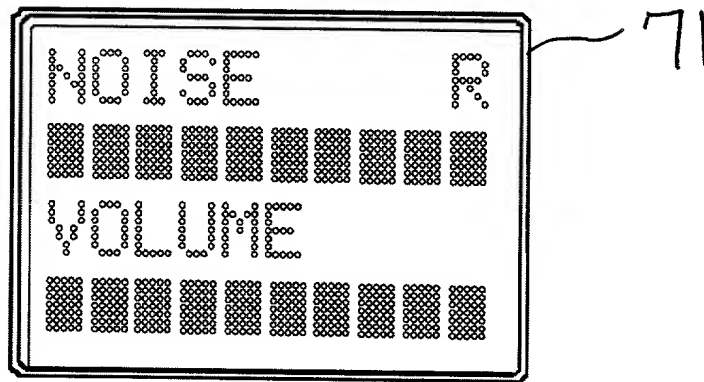


FIG. 5

**DECLARATION AND POWER OF ATTORNEY**

As the below-named inventors, we hereby declare that:  
our residence, post office address, and citizenship are as stated below next to our names.

We believe we are the original, first and joint inventors of the subject matter which is claimed  
and for which a patent is sought on the invention entitled

**HEARING TEST APPARATUS AND  
METHOD HAVING AUTOMATIC STARTING FUNCTIONALITY**

the specification which is being filed on even date herewith.

We hereby state that we have reviewed and understand the contents of the above-identified  
specification, including the claims.

We acknowledge the duty to disclose information which is material to the examination of this  
application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

And we hereby appoint:

the address and telephone number of each of whom is McAndrews, Held & Malloy, Ltd, 500 West  
Madison Street, 34th Floor, Chicago, Illinois 60661, 312-707-8889, as our attorneys with full power of  
substitution and revocation to prosecute this application and to transact all business in the Patent and  
Trademark Office connected therewith.

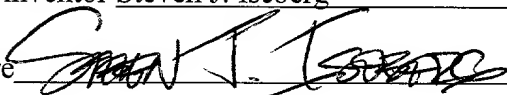
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We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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